Exactech®

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FEB - 8 2001

Exactech, Inc.
Tecres Cemex® System
Bone Cement

K000943

510(k) Summary of Safety and Effectiveness

510(k): **#K000943**

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

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FDA Establishment Number 1038671

Contact: Gary J. Miller, Ph.D.
V.P. of Research and Development

Date: August 11, 2000

Exactech, Inc.
Tecres Cemex® System
Bone Cement

510(k) Summary of Safety and Effectiveness

Trade Name: Cemex System Gun Application Version

Common Name: Bone Cement

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer
CMW3	CMW Laboratories (Distributed by Dow Corning Wright)
Simplex P	Howmedica
Palacos R	Merck (Distributed by Smith & Nephew)
Dough-Type	Zimmer

INTENDED USE

CEMEX SYSTEM bone cement is intended to be used for the fixation of artificial joint prostheses to host bone.

INDICATIONS FOR USE

CEMEX SYSTEM bone cement is indicated for the fixation of protheses to bone in orthopaedic musculoskeletal procedures for osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, tramatic arthritis, congenital deformities, avascular necrosis, post-traumatic degenerative problems of the hip, sickle cell anemia, osteoporosis, collagen disease and for the revision of previous arthroplasty procedures.

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CONTRAINDICATIONS

CEMEX SYSTEM bone cement is contraindicated in infectious arthritis and in active infection of the joint(s) to be replaced. Use of the bone cement is also contraindicated where the loss of musculature or neuromuscular compromise in the affected limb would render the surgical procedure unjustifiable.

CEMEX SYSTEM bone cement is contraindicated in patients who are allergic to any of its components.

DEVICE DESCRIPTION

Cemex System is an integrated system for the preparation and application of polymethylmethacrylate (PMMA) bone cement. The system consists of a liquid monomer component and dry polymer powder packaged in a clear plastic mixing/application device. The product is offered in 60 g and 80 g sizes.

The liquid monomer component is enclosed in a glass vial to separate it from the dry powdered component. The ratio between the powder and liquid components is approximately 3:1. *Table 1* below describes the basic ingredients of the polymer and monomer components.

System Component	Composition	%
Powder (polymer)	Polymethymethacrylate	85% w/w
	Barium Sulfate	12% w/w
	Benzoyl Peroxide	3% w/w
Liquid (monomer)	Methylmetacrylate	98.2% w/w
	N-N Dimethyl-p-Toluidine	1.8% w/w
	Hydroquinone	75 ppm

Table 1

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The product is double-packaged in unitary blister packs with Tyvek® lids. The outer packaging is a heavy weight cardboard box. The name, size, material composition, lot/serial information, sterility status and expiration date are indicated on the inner and outer labeling.

The liquid component is sterilized by a membrane filtration technique and placed into a glass vial at the manufacturing site. The Sterility Assurance Level (SAL) of the liquid component is 10^{-3}. The powdered component is sterilized by ethylene oxide (ETO) to a (SAL) of 10^{-6} at an off-site contract sterilization facility after the liquid and powdered components are incorporated into the mixing/application assembly.

Mixing and Application

Use of Cemex System bone cement takes place in two consecutive stages. During the first stage, the glass ampoule containing the liquid monomer is broken to allow the component to flow into the chamber containing the powdered constituents. The device is then used as a closed manual mixing device. Mixing is accomplished by firmly striking the device against the palm of the hand and rotating at each strike. Because no direct contact is made between the components and the user, volitile release into the local environment and possibility of contamination is minimized. In the second stage, the container is attached to an application gun device and used as a syringe while the cement is still in a semi-fluid state. The transparency of the mixing device provides for preliminary inspection of the suitability of the cement components and the visualization of the mixing and application stages as required by ISO 5833. Detailed instructions for use and precaution/warning information is outlined in the instruction leaflet provided with the product.

SUBSTANTIAL EQUIVALENCY SUMMARY:

Tecres Cemex System bone cement has similar indications for use and contraindications for use as other bone cements currently marketed in the United States. These predicate devices include "Simplex P" by Howmedica, "CMW 3" by Dow Corning Wright, "Dough" by Zimmer, and "Palacos R" by Smith & Nephew. Several of the predicate devices are indicated for the fixation of pathological fractures but Cemex System is not indicated for this application.

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Cemex System bone cement is similar technologically to these predicate devices in composition, material properties and performance characteristics. The chart on the following page compares the constituents of Cemex System with the other legally marketed bone cements. In addition to the compositional similarities, Cemex System like the predicate products, meets the requirements for acrylic bone cement for viscosity, polymerization temperature, elastic modulus, strength and viscoelastic properties as specified in ASTM F451 and ISO 5833.

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Distributor & *Model*	**Exactech** ***Cemex System***	**Howmedica** ***Simplex P Radiopaque***	**Dow Corning Wright** ***CMW3***	**Zimmer** ***Dough Radiopaque***	**Smith & Nephew** ***Palacos R Radiopaque***
Powder Components	Polymethymethacrylate 85% w/w Barium Sulfate 12% w/w Benzoyl Peroxide 3% w/w	Polymethymethacrylate 15 % w/w Methyl methacrylate-Styrene-copolymer 75 % w/w Barium Sulfate, U.S.P 10% w/w	Polymethymethacrylate 87.8% w/w Barium Sulfate 10% w/w Benzoyl Peroxide 2.2% w/w	Polymethymethacrylate 89.25% w/w Barium Sulfate 10% w/w Benzoyl Peroxide 0.75% w/w	Polymethymethacrylate (containing chlorophyll) 84 % w/w Benzoyl Peroxide 1% w/w Zirconium Dioxide 15% w/w
Liquid Components	Methylmetacrylate 98.2% w/w N-N Dimethyl-p-Toluidine 1.8% w/w Hydroquinone 75 ppm	Methylmetacrylate 97.4% v/v N-N Dimethyl-p-Toluidine 2.6% v/v Hydroquinone 75 ± 15 ppm	Methylmetacrylate 98.07% w/w N-N Dimethyl-p-Toluidine 0.99% w/w Hydroquinone 15 - 20 ppm Ethyl Alcohol 0.92 % w/w Ascorbic Acid 0.02% w/w	Methylmetacrylate 97.25% w/w N-N Dimethyl-p-Toluidine 2.75% w/w Hydroquinone 75 ± 10 ppm	Methylmetacrylate 98% w/w N-N Dimethyl-p-Toluidine 0.02% w/w Chlorophyll 0.002% w/w

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2001

Gary J. Miller, Ph.D.
Executive Vice President
Research & Development
Exactech®
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K000943
Trade Name: Cemex System Gun Application Version
Product Code: LOD
Regulatory Class: II
Dated: November 19, 2000
Received: November 21, 2000

Dear Dr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Inc.
Tecres Cemex® System Bone Cement
Premarket Notification – Traditional 510(k)

Indications for Use

510(k) Number: K000943

Device Name: Tecres Cemex System

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Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K000943

Prescription Use ✓ or Over the Counter Use _____